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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

M41060

60 8th Street, N.E.
Atlanta, Georgia 30309

August 17, 2000

VIA Federal Express

J. Luckey Welsh Jr., President & CEO
Southern Regional Medical Center
300 W. 27th Street
P. O. Box 1408
Lumberton, NC 28359

WARNING LETTER
(00-ATL-59)

Dear Mr. Welsh:

On July 28 & 31, 2000, the Food and Drug Administration conducted an inspection of your medical oxygen transfilling facility, Health Horizons Uniforms and Medical Equipment Inc., located in Lumberton, North Carolina. Our investigators documented significant deviations from the Current Good Manufacturing Practice Regulations (GMPs) as set forth in Title 21 of the Code of Federal Regulations (21 CFR), Parts 210 and 211. These deviations cause your transfilled drug product, Oxygen, USP, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

You have failed to assure that all medical oxygen transfilled and distributed by your facility conforms to the appropriate final specifications prior to release. You have failed to test or verify the results of each lot of bulk oxygen to determine conformance with appropriate specification for identity and strength. You have failed to appropriately calibrate and assure the accuracy of the [redacted] Oxygen Analyzer currently in use. The calibration standard in use is of an unknown purity. No certificate of analysis is available for the Nitrogen reference standard used to zero the [redacted] analyzer. No zero or span readings were taken on the [redacted] on 3/24/00, but lots 0841880, 08418900, and 08419000 of liquid oxygen were released and shipped to users.

You have failed to maintain adequate batch production and control records to document each significant step in the transfilling of your drug product. No odor testing is performed on home cryogenic units of Oxygen, USP prior to release to end-users. Records documenting calibration and maintenance of your oxygen analyzer are not maintained. You have failed to perform adequate pre-fill operations on each high-pressure cylinder prior to filling. On 7/26/00, high-pressure oxygen lot 20804200 with a recorded purity of 98% for 13 E cylinders

was released to end users despite the low purity value. Review of the filling record by the service technician was not adequate to detect the low purity value.

You have failed to establish detailed written procedures to cover the various aspects of your transfilling operation. The only procedures available were seriously deficient and were not indicative of the operations currently conducted at your firm. You have failed to establish written procedures for the calibration of vacuum gauges and thermometers. No documentation is available to show that vacuum gauges and thermometers have ever been calibrated. You have failed to establish written procedures to officially designate a Quality Control Unit that has the responsibility, authority, and training to perform Quality functions at your firm. The established written procedures currently being used at your firm fail to specify implementation dates and do not identify the person(s) who wrote, reviewed, and approved the procedures.

You have failed to ensure that each person engaged in the manufacture, processing and transfilling of this drug product, and each person responsible for supervising these activities, has the education, training, and experience to enable that person to perform their assigned functions in such a manner as to provide assurance that your drug product has the quality and purity that it purports or is represented to possess. This training must be in the particular operation that the employee performs and include current good manufacturing practice as it relates to the employee's functions. Production records have been routinely reviewed and approved by personnel with no training in, or knowledge of, the applicable requirements. The person who was in-charge of the overall filling operations [redacted], is no longer employed with your firm.

At the conclusion of the inspection, our investigators issued their Inspectional Observations (FDA 483) findings to Mr. Edward A. Henderson, Assistant Manager, and discussed their findings. A copy of the FDA 483 is enclosed for your review. Neither the above discussion of deficiencies, nor the FDA 483, should be construed as an all-inclusive list of violations that may be in existence at your firm. It is your responsibility to ensure that all requirements of the Act are being met at this facility.

You should take immediate action to correct these violations. Failure to promptly correct these deviations may result in legal sanctions provided by law such as product seizure and/or injunction, without further notice to you. Federal agencies are advised of the issuance of warning letters involving drugs so that they may take this information into account when considering the award of contracts.

You are requested to notify this office in writing within fifteen (15) working days of receipt of this letter of all steps you have taken, or intend to take, to correct the noted violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your response should also address any proposed actions regarding any oxygen lots currently in distribution, which have not been properly tested. Your response should be directed to the Food and Drug Administration, Atlanta District Office, 60 8th Street N.E., Atlanta, GA 30309, Attention: Karen Y. Dodson, Compliance Officer.

Sincerely,

Ballard H. Graham, Director
Atlanta District

Enclosure

cc: Edward A. Henderson, Assistant Manager
Health Horizons Uniform & Medical Equipment Inc.
2002 North Cedar Street
Suite A
Lumberton, North Carolina 28358